1. **Purpose**
   1.1. The purpose of this report is to document the report of the execution of PTL-0025A for the substantiation of the sterilization dose for the gamma radiation sterilization process for the M-Close™ Kit (see Attachment A) that is manufactured by New Wave Endo.
2. **Scope**
   2.1. New Wave Endo provided the M-Close Kit (REF 27-101) in its normal packaging configuration including the sterile barrier pouch and single unit boxing at the time of sterilization. In preparation for a planned family of kits, all of which will include the M-Close Kit plus various combinations of an anesthesia needle, extension microtubing set, and optional pre-sterilized and separately packaged accessories that will not be irradiated by gamma radiation, the M-Close Kit pouch subjected to the Gamma Sterilization Protocol (PTL-0025A) included the M-Close Kit handle assembly, guidewire and guidewire advancer, the anesthesia needle and a two-foot length of extension micro-tubing.
   2.2. The verification dose was delivered by Steris's Gamma Radiation facility located at: 2500 Commerce Drive, Libertyville, IL 60048
   2.3. Nominal sterilization dosing in preparation for Bacteriostasis/Fungistasis testing was performed by Steris's Gamma Radiation facility located at 1800 Industrial Drive, Libertyville, IL 60048.
   2.4. Microbiological testing was performed by LGGS: 15370 CR 565A, Suite A, Groveland FL 34736
   2.5. The M-Close Kit will be released for routine sterilization following:
      - Dose substantiation as addressed in the protocol and this report,
      - Determination of the maximum acceptable dose (see Protocol PTL-0025B),
      - Performance qualification (PQ) (see Protocol PTL-0025C).

3. **References**

Document Number	Document Title
ANSI/AAMI/ISO11137-1:2006/(R)2010	*Sterilization of healthcare products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
ANSI/AAMI/ISO 11137-2:2013	*Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*
ISO 13004:2013	*Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax^{SD}*
ANSI/AAMI/ISO 11737-1:2006	*Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products*
ANSI/AAMI/ISO 11737-2:2009	*Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
PTL-0025B	*Radiation Sterilization - Process Definition (Maximum Acceptable Dose) - M-Close*
PTL-0025C	*Radiation Sterilization - Performance Qualification M-Close Kit (Dose Map)*

4. Background and General Information

4.1. Process and Equipment Characterization

4.1.1. The sterilization dose for M-Close Kit™ is being determined based on substantiation of 30 kGy using the VDmax30 method as described in ANSI/AAMI/ISO TIR13004:2013. Equipment to deliver and verify the consistency and uniformity of the applied dose for each lot is the responsibility of the sterilization facility.

4.1.2. Upon successful substantiation of the 30 kGy sterilization dose, the product intended for release for human or animal use will be irradiated using gamma irradiation between the minimum dose (30 kGy) and the maximum allowable dose (50 kGy once established).

4.2. Product Definitions

4.2.1. The M-Close Kit consists of a handle which is a suture delivery system, a 24" micro-bore tubing extension set, a guidewire and a guidewire feeder, that has been designed by New Wave Endo. It also includes an FDA cleared 20 Ga local anesthesia needle as a convenience for the user. It will be provided as a sterile single-use device for human use. A pre-packaged, pre-sterilized, single use, FDA cleared bandage for use after the surgical port is closed is included with kit, but it is added to the unit box after return from the sterilization process and prior to commercial distribution.

4.2.2. New Wave Endo has previously conducted a sterilization substantiation for the sterilization dose of 30 kGy for the M-Close which was documented in RPT-0013A. Although, not previously identified as a "kit" in the prior validation report, it included the same elements as the current kit.

4.2.3. This is the only suturing product that New Wave Endo currently produces. Other members in the product family may include a different anesthesia needle, microtubing extension set, and other accessory items, pre-sterilized, separately packaged, and provided as a convenience. These additional items will not be subjected to gamma radiation, but added to the unit box, or the 5-unit box post sterilization.

4.2.4. If New Wave Endo develops other products and intends to use gamma sterilization at the same or other substantiated dose, this document may be modified to identify the product, process and irradiation levels for each product in tabular format for clarity.

4.2.5. Representative Product

Since the M-Close Kit is the only product in the product family at the current time, it will be the representative product for substantiating the sterilization dose. The components are combined to form the M-Close Kit, so all these components are tested together. This will be a sample item portion (SIP) of one (1). In configurations where the anesthesia needle or the micro-tubing extension is shorter or not included in the sterile package, the results of the validation will still be valid since the only effect of the subcomponent emissions will be to reduce the bioburden and the product density subjected to the same validated dose of gamma radiation.

5. Sample Requirements

5.1. Reference Table 1 for a summary of samples used.

Table 1: Sample Sizes

Testing	M-Close™ Kit (REF 27-101)
Bioburden Testing	10 from each: Lot C1521-1, Lot C1521-2, Lot C1521-3
Bioburden Recovery	5 units drawn from bioburden test units Lot # C1521-1 post testing via exhaustive method
Test of Sterility Validation (B/F)	3 from Lot C1521-4
Verification Dose/Tests of Sterility	20 from Lot # D0521

6. For Verification Dosing

6.1. Dosimeters accurate in a minimum range of 5 -35 kGy.

6.2. The load configuration for verification dosing consisted of the product samples being shipped in a corrugated box 13" x 13" x 13" containing three 5-unit boxes. The 5-unit boxes were removed from the shipping box for irradiation at the verification dose, replaced and forwarded directly to the sterility test lab. Although the protocol only requires 10 test units for sterility, the extra five units were sent as a backup in case there was a laboratory error resulting in possible contamination of 1 or more units.

7. Responsibilities

7.1. New Wave Endo:

- Prepared the protocol.
- Reviewed and approved the protocol.
- Prepared the test samples.
- Packaged the test samples.
- Shipped test samples to the locations specified in this protocol.
- Coordinated the testing of the samples.
- Reviewed test data.
- Prepared the final report.
- Reviewed and approved the final report.

7.2. Bioburden and Sterility Test Laboratory

- Performed the bioburden testing.

- Performed the tests for bioburden recovery, B/F sterility validation, and test of sterility.
- Provided test results.
- Will perform quarterly dose audit tests for bioburden (10 units) and sterility (10 units).

7.3. Sterilization Company

- Irradiated the test samples at the verification dose specified on the form (±10%)
- Ensured that all equipment was calibrated and maintained in accordance FDA QSR, ISO 13485, and ISO 11137 requirements.
- Provided dose documentation.
- Shipped irradiated test samples directly to the Sterility Test Laboratory.

8. Instrumentation Calibration / Certification

8.1. All the critical instrumentation for laboratory testing were calibrated per Bioburden and Sterility Test Laboratories Standard Operating Procedures and traceable to the National Institute of Standards and Technology (NIST), when applicable.

8.2. All the critical instrumentation (dosimeters, timing devices, gauges, etc.) for the irradiator and ancillary equipment were calibrated per Sterilization Company's Standard Operating Procedures and traceable to the National Institute of Standards and Technology (NIST), when applicable.

9. Procedure

9.1. M-Close™ Units (REF 27-101)

9.1.1. A total of 30 unsterilized M-Close Kit units from three (3) different lots: 10 from lot C1521-1, 10 from lot C1521-2, and 10 from lot C1521-3, were manufactured and packaged by New Wave Endo per the defined manufacturing process procedures for bioburden testing. These procedures are identified in the corresponding Device History Records.

9.1.2. Three (3) additional samples from lot C1521-4, part of a larger lot produced for design verification activities, were sterilized by gamma at a minimum dose of 30 kGy at the sterilization facility in Libertyville IL. These units were used for Bacteriostasis/Fungistasis method suitability testing.

9.1.3. Ten units of lot D0521 were sent to the sterilization facility in Libertyville IL and were irradiated at the target verification dose of 11.30 $\pm$ 10%; i.e. between 10.20 and 12.40 kGy. The actual applied dose was between 10.29 and 10.65 kGy which meets the target requirements for dose verification. An extra 5 units were sent as a backup in case of laboratory error post irradiation.

9.1.4. Ten additional unsterilized units from lot D0521 were sent directly to the bioburden test facility for bioburden testing.

9.1.5. These 53 samples were shipped to the same Test Laboratory at various times during the validation period for bioburden, correction factor, bacteriostasis/fungistasis, and sterility test activities.

9.2. Bioburden Testing

9.2.1. The Bioburden and Sterility Test Laboratory performed the bioburden validation using the repetitive recovery method per ISO 11737-1 to determine the recovery efficiency of the method. From the recovery efficiency, a bioburden correction factor was determined. Five sample units were used to determine the bioburden recovery factor.

9.2.2. Following the bioburden validation, 10 M-Close Kit samples from each of three lots were tested for bioburden using the method validated for measuring aerobes and fungi colony forming units, CFU's.

9.2.3. Since the M-Close Kit does not contain liquid and does not have areas that are not exposed to oxygen, obligate anaerobes are not likely to be present in the bioburden, so testing for anaerobes was not included. Other microorganisms such as spore-formers are a subset of aerobes or anaerobes and would be captured in the bioburden testing so further characterization is not required.

9.2.4. The bioburden count was determined from 10 samples from each of three lots, averaged, and was then corrected using the correction factor determined in the validation. The verification dose could have been obtained from Table 5 of ANSI/AAMI/ISO 11137- 2:2013, i.e. 21.3 kGy for a bioburden of 103.6 CFU to ensure and Sterility Assurance Level of 10^{-6}. However, to provide greater assurance of sterility, an overkill dose of 30 kGy was chosen for the M-Close Kit. This higher sterilization dose was selected and substantiated following the procedures in ISO 13004: 2013.

9.3. Verification Dose Experiment and Tests of Sterility

9.3.1. Upon determination of the verification dose, New Wave Endo shipped 15 M-Close Kit samples from a lot to the Irradiator for dosing at the verification dose (11.3 kGy ±10%) determined in ISO 13004: 2013, Table 9. The test for sterility requires only 10 units but the additional 5-units were irradiated at the low dose to provide a backup in case there was an error at the sterility testing facility requiring additional replacement samples.

9.3.2. The growth medium for both the B/F and Sterility Test was a soybean casein digest medium (SCBD), covering the entire device, incubated at 22.5 + 2.5°C for a duration of 5 days, per the protocol.

10. DATA ANALYSIS

10.1. The average Recoverable Aerobic and Fungi CFU's for the three bioburden test lots are shown in Table 2 below:

TABLE 2

Lot	Average Aerobic CFU	Average Fungi CFU	Average Total CFU
C1521-1	47.6	17.2	64.8
C1521-2	42.1	18.5	60.6
C1521-3	134.2	51.2	185.4
Average	74.63	28.97	103.6

10.2. ISO 13004:2013, paragraphs 6.2.5.2 and 6.2.5.3 provides a method of evaluating the overall average bioburden in cases where any one of the batch (i.e.lot) averages is two or more times greater than overall average. As seen in Table 2, Lot C1521-3 has the highest total bioburden at 185.4 CFU's. Twice the average bioburden of 103.6 CFU's is 207.2. Thus, each of the batch average bioburdens is less than two times the overall average bioburden and, following 6.2.5.3-(b), the overall average bioburden, 103.6 CFU's, should be used to determine the $VD_{max}{}^{SD}$.

10.3. Table 3 in ISO 13004:2013 provides upper limits for average bioburden for a given sterilization dose. For average bioburdens between 45 and 220 CFU's (with an SIP = 1.0), which is the range where the 103.6 CFU overall average bioburden falls, the standard selected sterilization dose would be 22.5 kGy. However, an overkill dose may be applied to provide extra assurance of sterility against unexpectedly high bioburdens. New Wave Endo has opted to use the overkill method of sterilization by standardizing on 30 kGy doses for production runs of gamma irradiation in the past and will continue to do so for the M-Close Kit family of products based on the current configuration of the test sample lots.

10.4. A reasonable question to address is what may have contributed to the higher reading for the third lot, C1521-3, compared to the two other lots used in the validation. There are three possible contributing factors to the higher reading.

10.4.1. Although assigned the same lot number, there were 10 Guidewire Advancer housings that were molded at the same facility and on the same equipment as the other housings which were made from Polycarbonate (PC) while the balance were formed from ABS. Both at the factory and at New Wave Endo, it is natural and likely that extra handling was involved during manufacturing, packaging, receipt, and evaluation of the alternative material compared to the larger ABS run for the other two test lot components.

10.4.2. Secondly, it was noticed that engineering at one point unwittingly used several of the M-Close handle assemblies from the C1521-3 to check a needle bending fixture in the controlled room prior to packaging. The extra handling may have contributed to three extra high readings for bioburden in that lot.

10.4.3. Finally, just prior to the third lot being removed from the controlled room following packaging, a decision to evaluate a small length of black suture material thread being knotted to the guidewire loop was made. The pouches were opened, ten six-inch lengths of suture were cut to length, knotted in place one to each guidewire in the lot, the pouch was resealed, and the seal was visually inspected. The roll of suture thread had been received and evaluated for potential suitability for use by engineering and marketing outside the controlled room recently before this time but was not handled with gloves in the controlled room until just prior to final packaging. This treatment represents a worst-case scenario in terms of mishandling of the product, but even so, it had a minor impact on the overall average bioburden and an even smaller resultant irradiation increase used in the verification dose.

11. Deviations

There were no deviations to the protocol.

12. Acceptance

12.1. The Bacteriostasis/ Fungistasis Test showed that the M-Close Kit samples do not inhibit microbiological growth.

12.2. The test of sterility showed that none of the 10 M-Close Kit samples, all of which included the suture "tail," subjected to the verification dose exhibited any growth. Thus, the sterilization dose is substantiated. None of the spare five verification dose units were used by the laboratory and these were returned to New Wave Endo and used for marketing demonstrations or R&D.

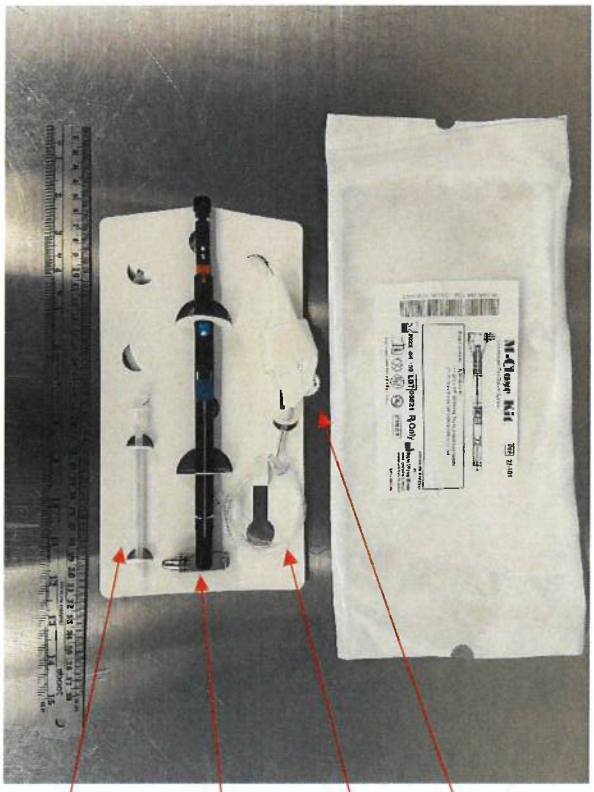
12.3. The completion of the sterilization validation will occur subsequent to the successful completion of PTL-0025B, *Radiation Sterilization - Process Definition (Maximum Acceptable Dose) - M-Close Kit* and PTL-0025C, *Radiation Sterilization - Performance Qualification M-Close.*

13. Attachments

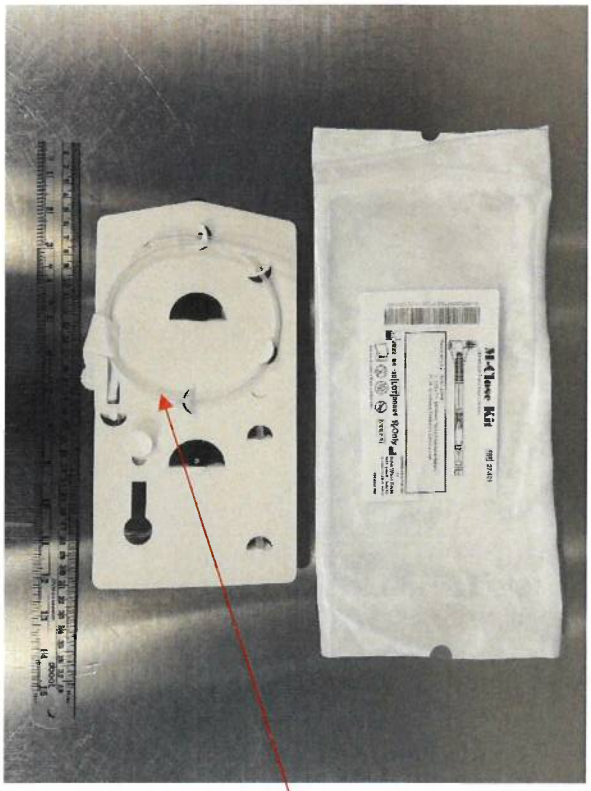
A. M-Close Kit (Image)
B. DHR's for the M-Close Kit lots used for testing
C. Bioburden Report
D. B/F Irradiation Record
E. B/F Report
F. Bioburden Recovery Final Report
G. Verification Dose Applied
H. Sterility Test Result

ATTACHMENT A
M-Close Kit (Images)

Front Side of Card



Rear Side of Card



1. 20ga Anesthesia Needle
2. M-Close Handle Assembly
3. Extension Set
4. Guidewire Advancer Assembly
5. Guidewire in Transport Tube

ATTACHMENT B

DHR's for the M-Close Kit Lots Used for Testing Bioburden, Recovery Factor, B/F and Sterility

(48 pages)

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: C1521-1

PRODUCT DESCRIPTION:	M-Close Kit		
CATALOG/ ITEM NUMBER:	27-101		
START DATE: (DDMTHYYYY)	15 MAR 2021	QUANTITY	
COMPLETION DATE: (DDMTHYYYY)	18 MAR 2021	ORDERED:	10
EXPIRATION DATE: (DDMTHYYYY)	31 MAR 2022	COMPLETED:	10
(Lot expires 12 months from assembly completion)		Outer (60 Units) Boxes	
Sterilization: Gamma		FULL	PARTIAL
		N/A	N/A

(Indicate partial qty, ex 1/6, 5/6, 7/12 etc.)

RELATED DOCUMENTS

DOCUMENT	REV	TITLE
MP-0002	1	Label Printing Procedure
MP-0011	2	Sealing Product Pouches
MP-0012	6	M-Close Pouch and Label
MP-0013	5	Needle-Plunger Assembly Procedure
MP-0015	6	M-Close Upper Body Assembly
MP-0017	8	M-Close Assembly
MP-0018	2	M-Close 60 Unit Shipping Assembly
MP-0019	2	TS-0006 DYMAX UV Light Source Set-up
MP-0020	1	Ultrasonic Cleaning
MP-0023	2	Micro Tubing Assembly
MP-0026	2	Bond Guidewire Loop
MP-0027	3	Body Upper Pre-work
MP-0028	4	Knob & Arm Assembly
MP-0030	2	Lower Halves Pre-work
MP-0032	2	T-Bar B Assembly
MP-0033	1	Guidewire Advancer Assembly
MP-0038	1	Guidewire Cinch Assembly
QP-0001	5	M-Close Final Inspection Procedure
QP-0004	1	Package Peel Test Procedure
QP-0008	4	M-Close Lot Release Test Procedure
QP-0010	1	Visual Inspection – Foreign Matter
QP-0011	1	Visual Inspection - Pouch Heat Seal
QP-0012	1	Needle Plunger Pressure Leak Testing Procedure
SOP-0054	1	Manufacturing Area Practices

IN PROCESS OPERATIONS SEQUENCE

ASSEMBLY OPERATION		INSPECTION CRITERIA			
ASSEMBLY OPERATION	PROCEDURE	INSPECTION DESCRIPTION	PROCEDURE TITLE	QUANTITY	FREQUENCY
Pouch Labeling	MP-0002	Label orientation, location, legible, lot# and use by date correct.	Label Printing Procedure	100%	At start of operation until completion
Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. Pouch, IFU, Accessory enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion
5-Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. 5 unit boxes enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

Boxing	MP-0018	60 units/box, labels applied, Gamma dot in outer shipper	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

PRODUCT TRAVELERS

PART#	DESCRIPTION	REV	QTY/ UNIT	Work Order # - WO-	Work Order # - WO-	Work Order# - WO-	Work Order# - WO-
DRW-0086	M-Close Pouched Assembly	3	1	21-03-009			
DRW-0052	M-Close Final Assembly	5	1	21-03-006			
DRW-0090	M-Close Shipping Assembly	3	1	21-03-013			
DRW-0109	20ga Needle Assembly	1	1	AN19002-2			
DRW-0113	Micro Tubing Assembly	2	1	20-10-018 ~~21-10-018~~	MFD. 17 MAR 2021 (MISPRINTED)		
DRW-0191	Guidewire Advancer Ass'y	1	1	21-03-010	NOTE: THESE UNITS ARE ABS HOUSINGS.		

ACCESSORY CONTENTS

PART#	DESCRIPTION	REV	QTY/ UNIT	Lot #	Use by Date	Lot #	Use by Date
DRW-0115	Covidien PHMB Telfa Pad	1	1	N/A	N/A		

STERILE BARRIER INSPECTION (add more rows as needed)

NEW WAVE ENDO SEAL

Date	Time	QTY	Settings (265°F@ 2.5 sec.) (Yes / No)	Lbs./Inch			(All Measurements ≥ .75 lb./in pass)		Comments	Inspector Initials:
				Left	Middle	Right	PASS	FAIL		
17 MAR 2021	2:30	1	YES	2.86	2.94	3.14	P			MV

POUCH VENDOR SEAL

Date Tested	Time Tested	QTY	Chevron Left	Chevron Right	Left	Right	PASS	FAIL	Comments	Inspector Initials:

VISUAL INSPECTION FOREIGN MATTER PROCEDURE: QP-0009

Date	Time	QTY	PASS	FAIL	Comments	Inspector Initials:
16MAR2021	1:15 PM	10	✓			DG

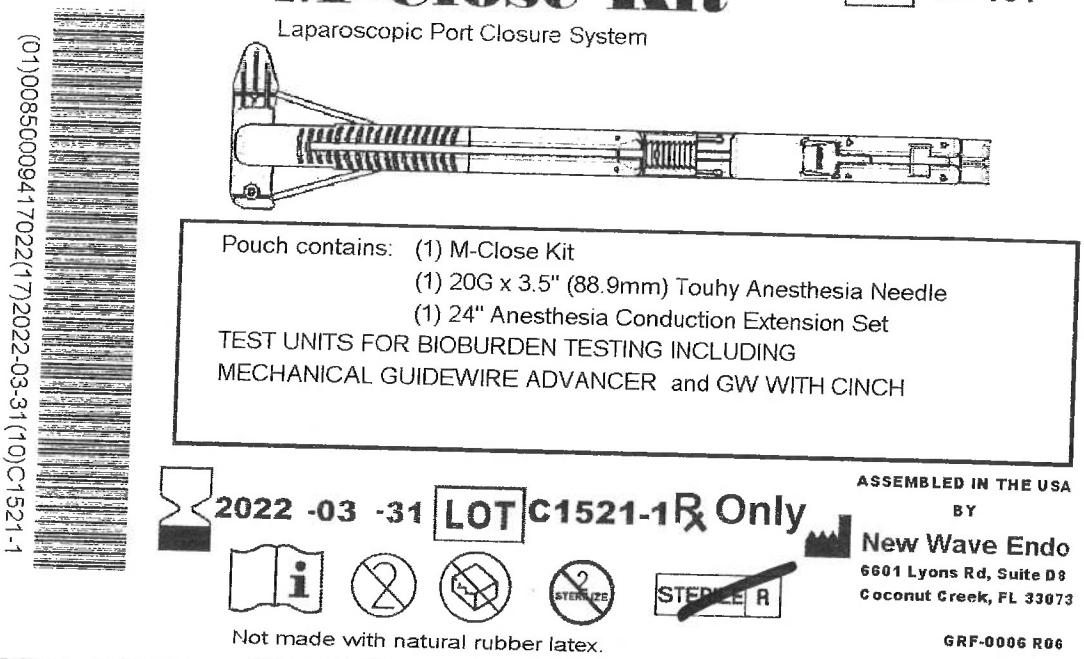
FINAL INSPECTION

DESCRIPTION	PROCEDURE TITLE	SAMPLE SIZE	RESULTS PASS	RESULTS FAIL	PERFORMED BY:
Verify that pouch labels are legible and include the following: Correct lot number, correct expiration date, bar code correct quantity as specified in label. All information should match this DHR.	QP-0008	100%	P		MJ
Verify pouch contains (1) M-Close Handle Ass'y, 20ga needle, tubing assembly, guidewire advancer assembly with guidewire. Verify that applicable labels are on the unit boxes. Verify that applicable labels are on the 5-unit boxes. Verify that applicable labels are on shipping boxes. — N/A MJ 16 MAR 2021	QP-0008	100%	P		MJ
Attach form FM-0013, M-Close Lot Release.	QP-0008	N/A	N/A*		MJ.
Attach copy of Irradiation Report to DHR.					N/A
Attach copies of all labels used to pages 5 and 6 (pouch, single unit box, 5-unit box, 60-unit box) and scan the barcode for each label on the corresponding line.	Pouch label: . Single unit box label: . 5-unit box label: . 60-unit box label: .				

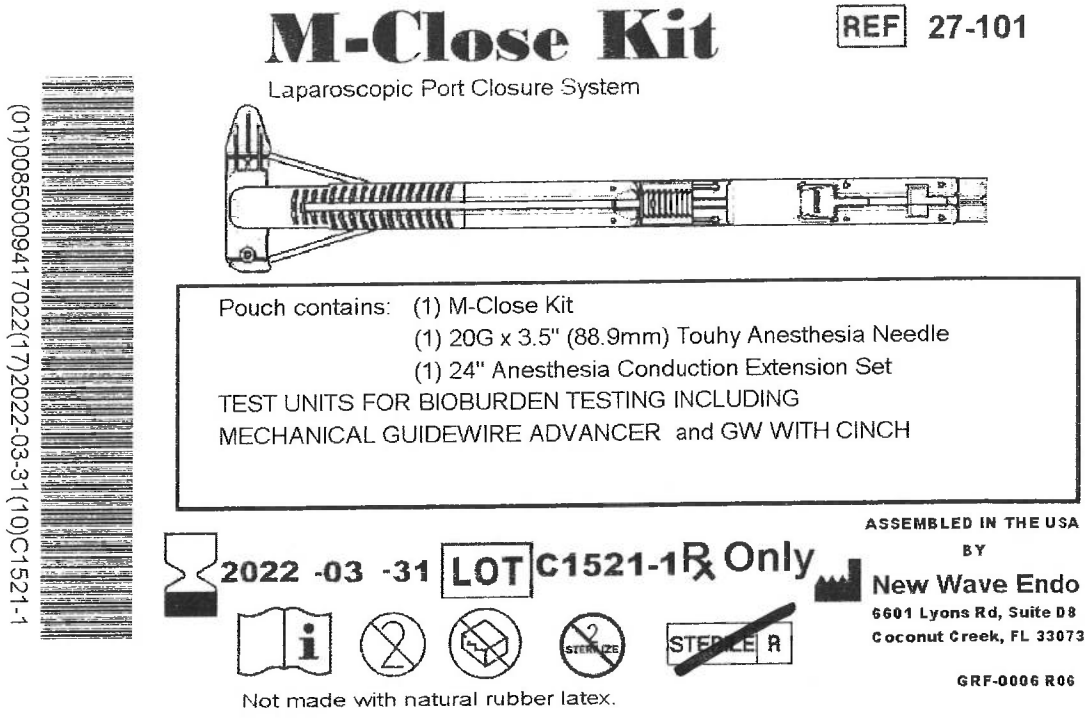
Comments:

* UNITS SENT FOR BIOBURDEN TESTING

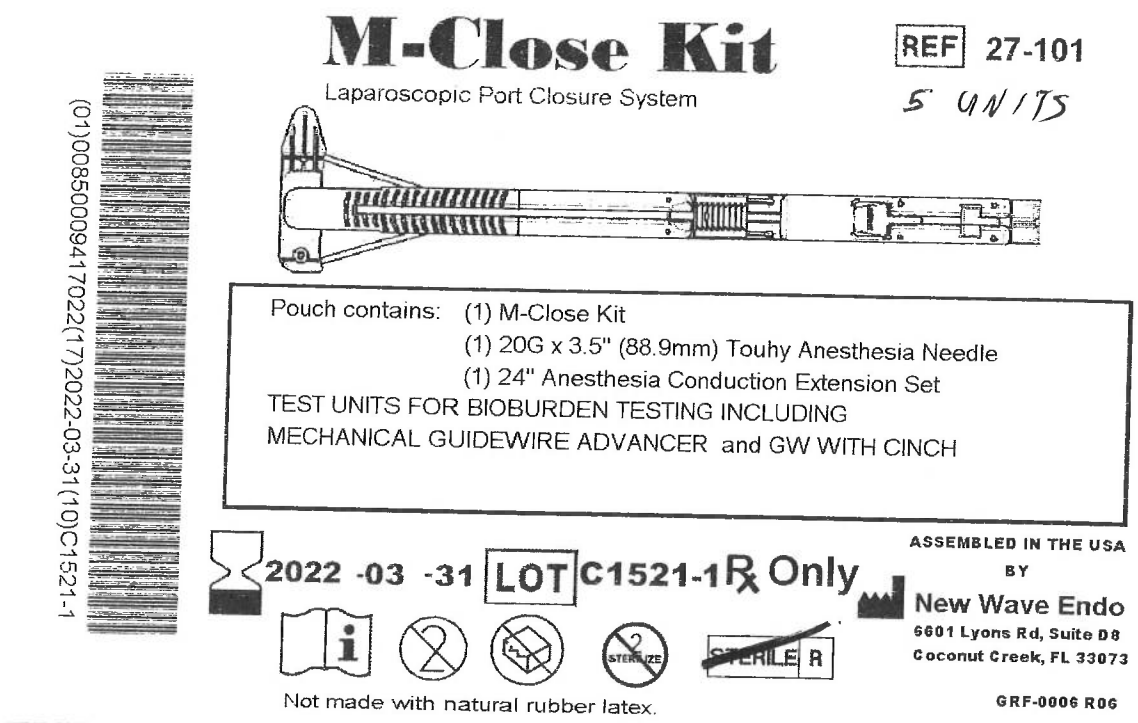
(Add additional pages if inspections exceed the space available above)



(Attach pouch label above)



(Attach single unit box label above)



(Attach 5-unit box label above)

N/A

(Attach 60-unit box label above)

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: C1521-2

PRODUCT DESCRIPTION:	M-Close Kit		
CATALOG/ ITEM NUMBER:	27-101		
START DATE: (DDMTHYYYY)	15 MAR 2021	QUANTITY	
COMPLETION DATE: (DDMTHYYYY)	16 MAR 2021	ORDERED:	10
EXPIRATION DATE: (DDMTHYYYY)	~~31 MAR 2021~~ 15 MAR 2021 ~~31 MAR 2021~~	COMPLETED:	10
(Lot expires 12 months from assembly completion)		Outer (60 Units) Boxes	
Sterilization: Gamma		FULL	PARTIAL
		N/A	N/A

(Indicate partial qty, ex 1/6, 5/6, 7/12 etc.)

RELATED DOCUMENTS

DOCUMENT	REV	TITLE
MP-0002	1	Label Printing Procedure
MP-0011	2	Sealing Product Pouches
MP-0012	6	M-Close Pouch and Label
MP-0013	5	Needle-Plunger Assembly Procedure
MP-0015	6	M-Close Upper Body Assembly
MP-0017	8	M-Close Assembly
MP-0018	2	M-Close 60 Unit Shipping Assembly
MP-0019	2	TS-0006 DYMAX UV Light Source Set-up
MP-0020	1	Ultrasonic Cleaning
MP-0023	2	Micro Tubing Assembly
MP-0026	2	Bond Guidewire Loop
MP-0027	3	Body Upper Pre-work
MP-0028	4	Knob & Arm Assembly
MP-0030	2	Lower Halves Pre-work
MP-0032	2	T-Bar B Assembly
MP-0033	1	Guidewire Advancer Assembly
MP-0038	1	Guidewire Cinch Assembly
QP-0001	5	M-Close Final Inspection Procedure
QP-0004	1	Package Peel Test Procedure
QP-0008	4	M-Close Lot Release Test Procedure
QP-0010	1	Visual Inspection – Foreign Matter
QP-0011	1	Visual Inspection - Pouch Heat Seal
QP-0012	1	Needle Plunger Pressure Leak Testing Procedure
SOP-0054	1	Manufacturing Area Practices

IN PROCESS OPERATIONS SEQUENCE

ASSEMBLY OPERATION		INSPECTION CRITERIA			
ASSEMBLY OPERATION	PROCEDURE	INSPECTION DESCRIPTION	PROCEDURE TITLE	QUANTITY	FREQUENCY
Pouch Labeling	MP-0002	Label orientation, location, legible, lot# and use by date correct.	Label Printing Procedure	100%	At start of operation until completion
Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. Pouch, IFU, Accessory enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion
5-Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. 5 unit boxes enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

Boxing	MP-0018	60 units/box, labels applied, Gamma dot in outer shipper	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

PRODUCT TRAVELERS

PART#	DESCRIPTION	REV	QTY/ UNIT	Work Order # - WO-	Work Order # - WO-	Work Order# - WO-	Work Order# - WO-
DRW-0086	M-Close Pouched Assembly	3	1	21-03-011			
DRW-0052	M-Close Final Assembly	5	1	21-03-006			
DRW-0090	M-Close Shipping Assembly	3	1	21-03-013			
DRW-0109	20ga Needle Assembly	1	1	AN 19002-2			
DRW-0113	Micro Tubing Assembly	2	1	~~21-03-010~~	MFG. ENTRY IN WRONG BOX 20-10-018		
DRW-0191	Guidewire Advancer Ass'y	1	1	21-03-010	NOTE: THESE HAVE ABS HOUSINGS		

ACCESSORY CONTENTS

PART#	DESCRIPTION	REV	QTY/ UNIT	Lot #	Use by Date	Lot #	Use by Date
DRW-0115	Covidien PHMB Telfa Pad	1	1	N/A	N/A		

STERILE BARRIER INSPECTION (add more rows as needed)

NEW WAVE ENDO SEAL

Date	Time	QTY	Settings (265°F@ 2.5 sec.) (Yes / No)	Lbs./Inch			(All Measurements ≥ .75 lb./in pass)		Comments	Inspector Initials:
				Left	Middle	Right	PASS	FAIL		
17 MAR 2021	2:45	1	YES	3.34	3.12	3.18	P			MJ

POUCH VENDOR SEAL

Date Tested	Time Tested	QTY	Chevron Left	Chevron Right	Left	Right	PASS	FAIL	Comments	Inspector Initials:

VISUAL INSPECTION FOREIGN MATTER PROCEDURE: QP-0009

Date	Time	QTY	PASS	FAIL	Comments	Inspector Initials:
16 MAR 2021	3:00	10	✓			DB

FINAL INSPECTION

DESCRIPTION	PROCEDURE TITLE	SAMPLE SIZE	RESULTS PASS	RESULTS FAIL	PERFORMED BY:
Verify that pouch labels are legible and include the following: Correct lot number, correct expiration date, bar code, correct quantity as specified in label. All information should match this DHR.	QP-0008	100%	P		[signature]
Verify pouch contains (1) M-Close Handle Ass'y, 20ga needle, tubing assembly, guidewire advancer assembly with guidewire. Verify that applicable labels are on the unit boxes. Verify that applicable labels are on the 5-unit boxes. Verify that applicable labels are on shipping boxes.	QP-0008	100%	P		[signature]
Attach form FM-0013, M-Close Lot Release.	QP-0008	—	N/A		*
Attach copy of Irradiation Report to DHR.					N/A
Attach copies of all labels used to pages 5 and 6 (pouch, single unit box, 5-unit box, 60-unit box) and scan the barcode for each label on the corresponding line.	Pouch label: 01008500094170221720220331 10C1521-2 Single unit box label: 01008500094170221720220331 10C1521-2 5-unit box label: 01008500094170221720220331 10C1521-2 60-unit box label: N/A				

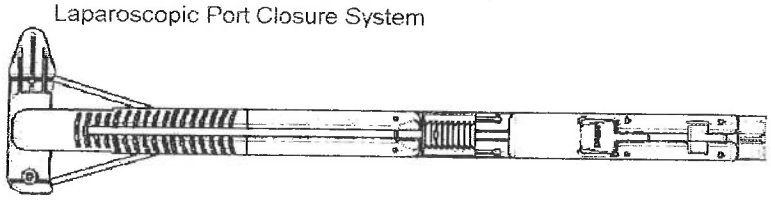
Comments: * UNITS SENT FOR BIOBURDEN TESTING.

(Add additional pages if inspections exceed the space available above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-2

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR BIOBURDEN TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-2 Rx Only

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

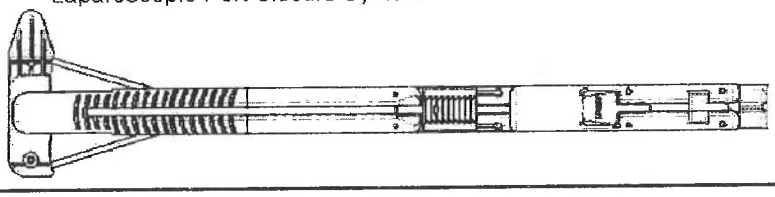
GRF-0006 R06

(Attach pouch label above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-2

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR BIOBURDEN TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-2 Rx Only

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

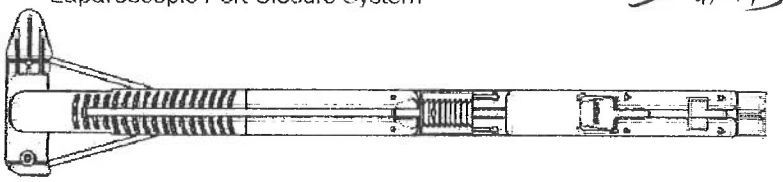
(Attach single unit box label above)

M-Close Kit

REF 27-101

5 UNITS

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-2

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR BIOBURDEN TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-2 Rx Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

(Attach 5-unit box label above)

N/A

(Attach 60-unit box label above)

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: C1521-3

PRODUCT DESCRIPTION:	M-Close Kit		
CATALOG/ ITEM NUMBER:	27-101		
START DATE: (DDMTHYYYY)	15 MAR 2021	QUANTITY	
COMPLETION DATE: (DDMTHYYYY)	16 MAR 2021	ORDERED:	10
EXPIRATION DATE: (DDMTHYYYY)	31 MAR 2022	COMPLETED:	10
(Lot expires 12 months from assembly completion)		Outer (60 Units) Boxes	
Sterilization: Gamma		FULL	PARTIAL
		N/A	N/A

(Indicate partial qty, ex 1/6, 5/6, 7/12 etc.)

RELATED DOCUMENTS		
DOCUMENT	REV	TITLE
MP-0002	1	Label Printing Procedure
MP-0012	6	M-Close Pouch and Label
MP-0013	5	Needle-Plunger Assembly Procedure
MP-0015	6	M-Close Upper Body Assembly
MP-0017	8	M-Close Assembly
MP-0018	2	M-Close 60 Unit Shipping Assembly
MP-0019	2	TS-0006 DYMAX UV Light Source Set-up
MP-0020	1	Ultrasonic Cleaning
MP-0023	2	Micro Tubing Assembly
MP-0026	2	Bond Guidewire Loop
MP-0027	3	Body Upper Pre-work
MP-0028	4	Knob & Arm Assembly
MP-0030	2	Lower Halves Pre-work
MP-0032	2	T-Bar B Assembly
MP-0033	1	Guidewire Advancer Assembly
MP-0038	1	Guidewire Cinch Assembly
QP-0001	5	M-Close Final Inspection Procedure
QP-0004	1	Package Peel Test Procedure
QP-0008	4	M-Close Lot Release Test Procedure
QP-0010	1	Visual Inspection – Foreign Matter
QP-0011	1	Visual Inspection - Pouch Heat Seal
QP-0012	1	Needle Plunger Pressure Leak Testing Procedure
SOP-0054	1	Manufacturing Area Practices
MP-0002	1	Label Printing Procedure

IN PROCESS OPERATIONS SEQUENCE					
ASSEMBLY OPERATION		INSPECTION CRITERIA			
ASSEMBLY OPERATION	PROCEDURE	INSPECTION DESCRIPTION	PROCEDURE TITLE	QUANTITY	FREQUENCY
Pouch Labeling	MP-0002	Label orientation, location, legible, lot# and use by date correct.	Label Printing Procedure	100%	At start of operation until completion
Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. Pouch, IFU, Accessory enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion
5-Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. 5 unit boxes enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

Boxing	MP-0018	60 units/box, labels applied, Gamma dot in outer shipper	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

PRODUCT TRAVELERS

PART#	DESCRIPTION	REV	QTY/ UNIT	Work Order # - WO-	Work Order # - WO-	Work Order# - WO-	Work Order# - WO-
DRW-0086	M-Close Pouched Assembly	3	1	21-03-012			
DRW-0052	M-Close Final Assembly	5	1	21-02-014			
DRW-0090	M-Close Shipping Assembly	3	1	21-03-013			
DRW-0109	20ga Needle Assembly	1	1	AN19002-2			
DRW-0113	Micro Tubing Assembly	2	1	20-10-018			
DRW-0191	Guidewire Advancer Ass'y	1	1	21-03-010	NOTE: THESE UNITS HAVE PC HOUSINGS, and a GW cinch "tail" attached to the GW loop.		

ACCESSORY CONTENTS

PART#	DESCRIPTION	REV	QTY/ UNIT	Lot #	Use by Date	Lot #	Use by Date
DRW-0115	Covidien PHMB Telfa Pad	1	1	N/A	N/A		

STERILE BARRIER INSPECTION (add more rows as needed)

NEW WAVE ENDO SEAL

Date	Time	QTY	Settings (265°F@ 2.5 sec.) (Yes / No)	Lbs./Inch			(All Measurements ≥ .75 lb./in pass)		Comments	Inspector Initials:
				Left	Middle	Right	PASS	FAIL		
17 MAR 2021	5:05	1	YES	3.12	2.98	3.10	P			DM

POUCH VENDOR SEAL

Date Tested	Time Tested	QTY	Chevron Left	Chevron Right	Left	Right	PASS	FAIL	Comments	Inspector Initials:

VISUAL INSPECTION FOREIGN MATTER PROCEDURE: QP-0009

Date	Time	QTY	PASS	FAIL	Comments	Inspector Initials:
~~17 MAR 2021~~	10:20	~~13~~ 10	/		only 10 from this lot # C1521-3	DB
		AA-17-MARCH 2021				

FINAL INSPECTION

DESCRIPTION	PROCEDURE TITLE	SAMPLE SIZE	RESULTS PASS	RESULTS FAIL	PERFORMED BY:
Verify that pouch labels are legible and include the following: Correct lot number, correct expiration date, bar code, correct quantity as specified in label. All information should match this DHR.	QP-0008	100%	✓		
Ensure that current IFU is used. Verify pouch contains (1) M-Close Handle Ass'y, 20ga needle, tubing assembly, guidewire advancer assembly with guidewire. Verify that applicable labels are on the unit boxes. Verify that applicable labels are on the 5-unit boxes. Verify that applicable labels are on shipping boxes.	QP-0008	100%	✓		
Attach form FM-0013, M-Close Lot Release.	QP-0008	N/A	N/A	N/A	[illegible]
Attach copy of Irradiation Report to DHR.					N/A
Attach copies of all labels used to pages 5 and 6 (pouch, single unit box, 5-unit box, 60-unit box) and scan the barcode for each label on the corresponding line.	Pouch label: 01008500094170221720220331 10C1521-3 Single unit box label: 01008500094170221720220331 10C1521-3 5-unit box label: 01008500094170221720220331 10C1521-3 60-unit box label: N/A				

Comments:

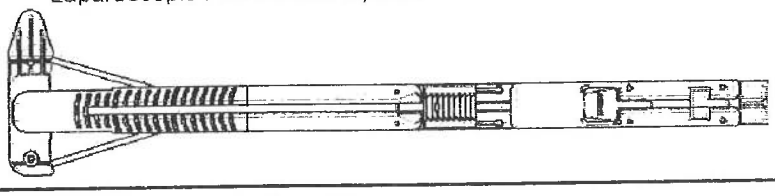
Units sent for bioburden testing

(Add additional pages if inspections exceed the space available above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-3

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR BIOBURDEN TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-3 Rx Only

STERILE R

Not made with natural rubber latex.

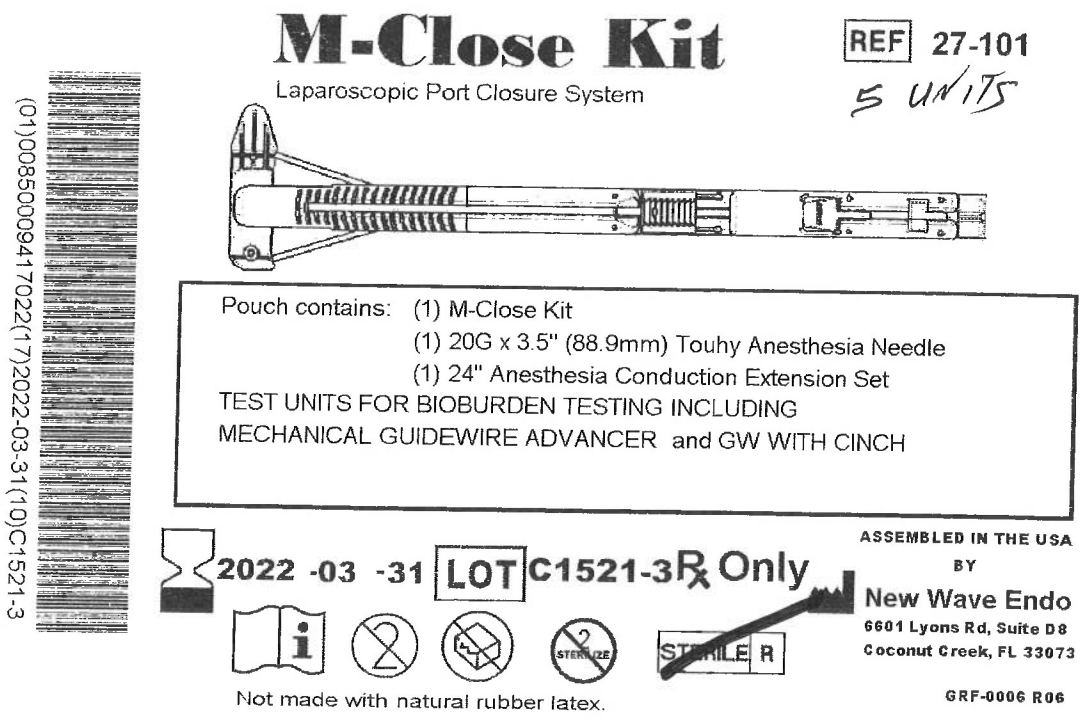
ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

(Attach pouch label above)

Same as above MM

(Attach single unit box label above)



(Attach 5-unit box label above)

N/A

(Attach 60-unit box label above)

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: C1521-4

PRODUCT DESCRIPTION:	M-Close Kit		
CATALOG/ ITEM NUMBER:	27-101		
START DATE: (DDMTHYYYY)	17 MAR 2021	QUANTITY	
COMPLETION DATE: (DDMTHYYYY)	17 MAR 2021	ORDERED:	3
EXPIRATION DATE: (DDMTHYYYY)	31 MAR 2022	COMPLETED:	3
(Lot expires 12 months from assembly completion)		Outer (60 Units) Boxes	
Sterilization: Gamma		FULL	PARTIAL
		N/A	N/A

(Indicate partial qty, ex 1/6, 5/6, 7/12 etc.)

RELATED DOCUMENTS

DOCUMENT	REV	TITLE
MP-0002	1	Label Printing Procedure
MP-0012	6	M-Close Pouch and Label
MP-0013	5	Needle-Plunger Assembly Procedure
MP-0015	6	M-Close Upper Body Assembly
MP-0017	8	M-Close Assembly
MP-0018	2	M-Close 60 Unit Shipping Assembly
MP-0019	2	TS-0006 DYMAX UV Light Source Set-up
MP-0020	1	Ultrasonic Cleaning
MP-0023	2	Micro Tubing Assembly
MP-0026	2	Bond Guidewire Loop
MP-0027	3	Body Upper Pre-work
MP-0028	4	Knob & Arm Assembly
MP-0030	2	Lower Halves Pre-work
MP-0032	2	T-Bar B Assembly
MP-0033	1	Guidewire Advancer Assembly
MP-0038	1	Guidewire Cinch Assembly
QP-0001	5	M-Close Final Inspection Procedure
QP-0004	1	Package Peel Test Procedure
QP-0008	4	M-Close Lot Release Test Procedure
QP-0010	1	Visual Inspection – Foreign Matter
QP-0011	1	Visual Inspection - Pouch Heat Seal
QP-0012	1	Needle Plunger Pressure Leak Testing Procedure
SOP-0054	1	Manufacturing Area Practices
MP-0002	1	Label Printing Procedure

IN PROCESS OPERATIONS SEQUENCE

ASSEMBLY OPERATION		INSPECTION CRITERIA			
ASSEMBLY OPERATION	PROCEDURE	INSPECTION DESCRIPTION	PROCEDURE TITLE	QUANTITY	FREQUENCY
Pouch Labeling	MP-0002	Label orientation, location, legible, lot# and use by date correct.	Label Printing Procedure	100%	At start of operation until completion
Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. Pouch, IFU, Accessory enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion
5-Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. 5 unit boxes enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

Boxing	MP-0018	60 units/box, labels applied, Gamma dot in outer shipper	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

PRODUCT TRAVELERS

PART#	DESCRIPTION	REV	QTY/ UNIT	Work Order # - WO-	Work Order # - WO-	Work Order# - WO-	Work Order# - WO-
DRW-0086	M-Close Pouched Assembly	3	1	21-03-014			
DRW-0052	M-Close Final Assembly	5	1	21-03-006			
DRW-0090	M-Close Shipping Assembly	3	1	SHIPPED TO STERIS FOR & along with LOT # THEN SHIPPED TO LOGS FOR B/E Testing			C2321
DRW-0109	20ga Needle Assembly	1	1	AN/9002-2			
DRW-0113	Micro Tubing Assembly	2	1	~~21-10-018~~ 20-10-018 WO. 17 MAR 2021 MISPRINTED			
DRW-0191	Guidewire Advancer Ass'y	1	1	21-03-010 - ABS material			

ACCESSORY CONTENTS

PART#	DESCRIPTION	REV	QTY/ UNIT	Lot #	Use by Date	Lot #	Use by Date
DRW-0115	Covidien PHMB Telfa Pad	1	1	N/A	N/A		

STERILE BARRIER INSPECTION (add more rows as needed)

NEW WAVE ENDO SEAL

Date	Time	QTY	Settings (265°F@ 2.5 sec.) (Yes / No)	Lbs./Inch			(All Measurements ≥ .75 lb./in pass)		Comments	Inspector Initials:
				Left	Middle	Right	PASS	FAIL		
N/A	N/A	N/A	N/A						NOT TESTED	
									ONLY 3 UNITS	
									GOING TO INSTATE	
									TEST LAB	

POUCH VENDOR SEAL

Date Tested	Time Tested	QTY	Chevron Left	Chevron Right	Left	Right	PASS	FAIL	Comments	Inspector Initials:
									N/A See	
									above	

VISUAL INSPECTION FOREIGN MATTER PROCEDURE: QP-0009

Date	Time	QTY	PASS	FAIL	Comments	Inspector Initials:
17 MAR 2021	10:30	3	✓			DB

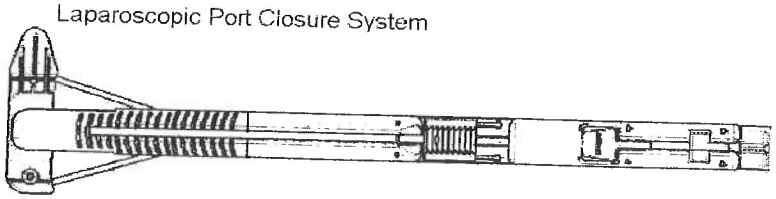
FINAL INSPECTION					
DESCRIPTION	PROCEDURE TITLE	SAMPLE SIZE	RESULTS PASS	RESULTS FAIL	PERFORMED BY:
Verify that pouch labels are legible and include the following: Correct lot number, correct expiration date, bar code, correct quantity as specified in label. All information should match this DHR.	QP-0008	100%	P		
Ensure that current IFU is used. Verify pouch contains **(1)** M-Close Handle Ass'y, 20ga needle, tubing assembly, guidewire advancer assembly with guidewire. Verify that applicable labels are on the unit boxes. Verify that applicable labels are on the 5-unit boxes. Verify that applicable labels are on shipping boxes.	QP-0008	100%	N/A	N/A	
Attach form FM-0013, M-Close Lot Release.	QP-0008	N/A		N/A	N/A
Attach copy of Irradiation Report to DHR.					See Lot C2321
Attach copies of all labels used to pages 5 and 6 (pouch, single unit box, 5-unit box, 60-unit box) and scan the barcode for each label on the corresponding line.	Pouch label: 01008500094170221720220331 10C1521-4 Single unit box label: 01008500094170221720220331 10C1521-4 5-unit box label: N/A 60-unit box label: N/A				
Comments:					

(Add additional pages if inspections exceed the space available above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-4

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR B/F TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-4 Rx Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

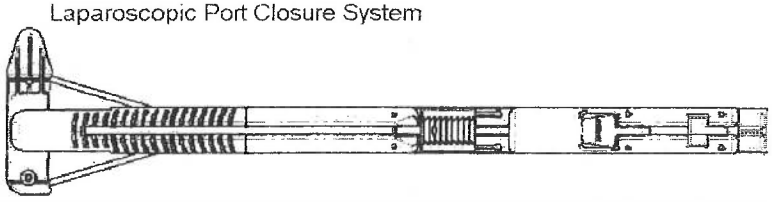
GRF-0006 R06

(Attach pouch label above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-4

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR B/F TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-4 Rx Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

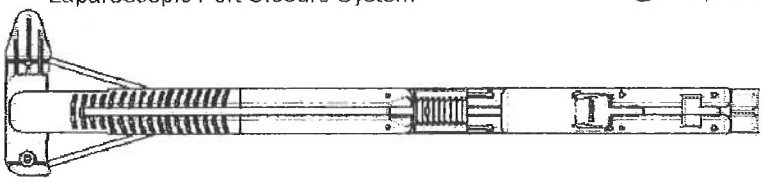
(Attach single unit box label above)

M-Close Kit

REF 27-101

3 UNITS

Laparoscopic Port Closure System



(01)00850009417022(17)2022-03-31(10)C1521-4

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR B/F TESTING INCLUDING
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -03 -31 LOT C1521-4 Rx Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

(Attach 5-unit box label above)

(Attach 60-unit box label above)

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: D0521

PRODUCT DESCRIPTION:	M-Close Kit		
CATALOG/ ITEM NUMBER:	27-101		
START DATE: (DDMTHYYYY)	05 APR 2021	QUANTITY	
COMPLETION DATE: (DDMTHYYYY)	05 APR 2021	ORDERED:	15
EXPIRATION DATE: (DDMTHYYYY)	30 APR 2022	COMPLETED:	15
(Lot expires 12 months from assembly completion)		Outer (60 Units) Boxes	
Sterilization: Gamma		FULL	PARTIAL
		15 in 13"X13"X13" shipper	0

(Indicate partial qty, ex 1/6, 5/6, 7/12 etc.)

RELATED DOCUMENTS		
DOCUMENT	REV	TITLE
MP-0002	1	Label Printing Procedure
MP-0012	6	M-Close Pouch and Label
MP-0013	5	Needle-Plunger Assembly Procedure
MP-0015	6	M-Close Upper Body Assembly
MP-0017	8	M-Close Assembly
MP-0018	2	M-Close 60 Unit Shipping Assembly
MP-0019	2	TS-0006 DYMAX UV Light Source Set-up
MP-0020	1	Ultrasonic Cleaning
MP-0023	2	Micro Tubing Assembly
MP-0026	2	Bond Guidewire Loop
MP-0027	3	Body Upper Pre-work
MP-0028	4	Knob & Arm Assembly
MP-0030	2	Lower Halves Pre-work
MP-0032	2	T-Bar B Assembly
MP-0033	1	Guidewire Advancer Assembly
MP-0038	1	Guidewire Cinch Assembly
QP-0001	5	M-Close Final Inspection Procedure
QP-0004	1	Package Peel Test Procedure
QP-0008	4	M-Close Lot Release Test Procedure
QP-0010	1	Visual Inspection – Foreign Matter
QP-0011	1	Visual Inspection - Pouch Heat Seal
QP-0012	1	Needle Plunger Pressure Leak Testing Procedure
SOP-0054	1	Manufacturing Area Practices
MP-0002	1	Label Printing Procedure

IN PROCESS OPERATIONS SEQUENCE					
ASSEMBLY OPERATION		INSPECTION CRITERIA			
ASSEMBLY OPERATION	PROCEDURE	INSPECTION DESCRIPTION	PROCEDURE TITLE	QUANTITY	FREQUENCY
Pouch Labeling	MP-0002	Label orientation, location, legible, lot# and use by date correct.	Label Printing Procedure	100%	At start of operation until completion
Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. Pouch, IFU, Accessory enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion
5-Unit Box Assembly	MP-0018	Label orientation, location, legible, lot# and use by date correct. 5 unit boxes enclosed.	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

NEW WAVE ENDO	DEVICE HISTORY RECORD	LOT NUMBER: D0521

Boxing	MP-0018	60 units/box, labels applied, Gamma dot in outer shipper	M-Close 60 Unit Shipping Assembly	100%	At start of operation until completion

PRODUCT TRAVELERS

PART#	DESCRIPTION	REV	QTY/ UNIT	Work Order # - WO-	Work Order # - WO-	Work Order# - WO-	Work Order# - WO-
DRW-0086	M-Close Pouched Assembly	3	1	21-04-017			
DRW-0052	M-Close Final Assembly	5	1	21-03-021			
DRW-0090	M-Close Shipping Assembly	3	1	N/A - see instructions in submittal to Steris AST for			
DRW-0096	Guidewire Feeder Assembly	2	1	24-04-005		description of shipping assy.	
DRW-0109	20ga Needle Assembly	1	1	AN19002-2	QP-0010	MCLOSE FINAL INSPECTION	
DRW-0113	Micro Tubing Assembly	2	1	21-02-020		21-04-002	

ACCESSORY CONTENTS

PART#	DESCRIPTION	REV	QTY/ UNIT	Lot #	Use by Date	Lot #	Use by Date
DRW-0115	Covidien PHMB Telfa Pad	1	1	N/A	N/A		

STERILE BARRIER INSPECTION (add more rows as needed)

NEW WAVE ENDO SEAL

Date	Time	QTY	Settings (265°F@ 2.5 sec.) (Yes / No)	Lbs./Inch			(All Measurements ≥ .75 lb./in pass)		Comments	Inspector Initials:
				Left	Middle	Right	PASS	FAIL		
05 APR 2021	1:50	1	YES	2.90	3.16	2.60	P			MJ
" "	2:04	1	YES	3.16	2.54	2.52	P			MJ

POUCH VENDOR SEAL

Date Tested	Time Tested	QTY	Chevron Left	Chevron Right	Left	Right	PASS	FAIL	Comments	Inspector Initials:
05 APR 2021	2:01	1	1.64	1.98	3.12	2.74	P			MJ

VISUAL INSPECTION FOREIGN MATTER PROCEDURE: QP-0009

Date	Time	QTY	PASS	FAIL	Comments	Inspector Initials:
05 APR 2021	2:30	15	✓			MJ

FINAL INSPECTION					
DESCRIPTION	PROCEDURE TITLE	SAMPLE SIZE	RESULTS PASS	RESULTS FAIL	PERFORMED BY:
Verify that pouch labels are legible and include the following: Correct lot number, correct expiration date, bar code, correct quantity as specified in label. All information should match this DHR.	QP-0008	100%			
Ensure that current IFU is used. Verify pouch contains (1) M-Close Handle Ass'y, 20ga needle, tubing assembly, guidewire feeder. Verify that applicable labels are on the unit boxes. Verify that applicable labels are on the 5-unit boxes. Verify that applicable labels are on shipping boxes.	QP-0008	100%			
Attach form FM-0013, M-Close Lot Release.	QP-0008	—	N/A		md.
Attach copy of Irradiation Report to DHR.					
Attach copies of all labels used to pages 5 and 6 (pouch, single unit box, 5-unit box, 60-unit box) and scan the barcode for each label on the corresponding line.	Pouch label: 01008500094170221720220430 10D0521 Single unit box label: 01008500094170221720220430 10D0521 5-unit box label: 01008500094170221720220430 10D0521 60-unit box label: N/A				

Comments:

These units are intended for sterilization validation on M-Close Kit, REF 27-101, which includes T-Bar-B, guidewire with cinch (DRW-0189) and suture pull added to loop, and guidewire advancer mechanism (DRW-0191) replacing the previous guidewire feeder. They are being sent to Steris AST Radiation Technology Center, 2500 Commerce Drive, Libertyville, IL 60048 for the verification dose under RRF submittal #10338z.

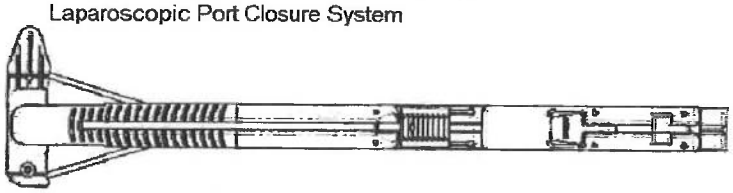
Post irradiation the units are being forwarded to LGGS Florida for sterility testing on 10 units. The extra 5 units are provided as insurance against a lab error during sterility testing.

(Add additional pages if inspections exceed the space available above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-04-30(10)D0521

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR VERIFICATION DOSE
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -04 -30 LOT D0521 ℞ Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

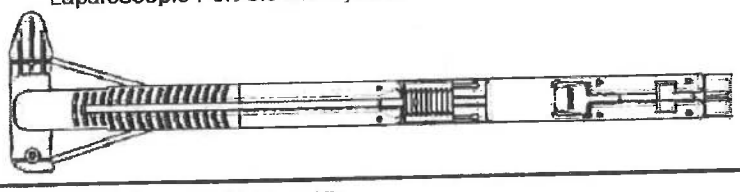
GRF-0006 R06

(Attach pouch label above)

M-Close Kit

REF 27-101

Laparoscopic Port Closure System



(01)00850009417022(17)2022-04-30(10)D0521

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR VERIFICATION DOSE
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

2022 -04 -30 LOT D0521 ℞ Only

STERILE R

Not made with natural rubber latex.

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

GRF-0006 R06

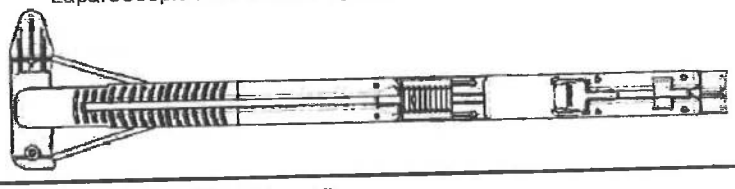
(Attach single unit box label above)

M-Close Kit

Laparoscopic Port Closure System

REF 27-101

Contains five (5) units



(01)00850009417022(17)2022-04-30(10)D0521

Pouch contains: (1) M-Close Kit
(1) 20G x 3.5" (88.9mm) Touhy Anesthesia Needle
(1) 24" Anesthesia Conduction Extension Set
TEST UNITS FOR VERIFICATION DOSE
MECHANICAL GUIDEWIRE ADVANCER and GW WITH CINCH

ASSEMBLED IN THE USA
BY
New Wave Endo
6601 Lyons Rd, Suite D8
Coconut Creek, FL 33073

2022 -04 -30 LOT D0521 Rx Only

STERILE R

GRF-0006 R06

Not made with natural rubber latex.

(Attach 5-unit box label above)

N/A

(Attach 60-unit box label above)

NEW WAVE ENDO

M-Close Final Inspection Record

Work Order # 21-04002 | Doc #: QP-0001 | QTY Starts: 15

MP #	Procedural Description	Work Step	Part # (BOM Qty)	Lot #	Qty. Rejected	Qty. Accepted	Initials (Each Operator)
QP-0001 Rev: 05	Manufacturing Line Clearance	4.1	IPA 70%				MA
	T-Bar Rotation	5.1.2	M-Close Handle Assembly DRW-0052 (1)	D0521	0	15	MA
	Plunger 1st stop retention	5.1.4			0	15	MA
	Plunger 1st stop weight suspension	5.1.6			0	15	MA
	Dual Lumen Inspection	5.1.9			0	15	MA
	Plunger 2nd stop retention	5.1.12			0	15	MA
	Plunger 2nd stop weight suspension	5.1.14			0	15	MA
	Plunger 2nd stop drop	5.1.16			0	15	MA
	Plunger head offset weight lift	5.1.18			0	15	MA

NEW WAVE ENDO	M-Close Final Inspection Record	
Work Order # 21-04-002	Doc #: QP-0001	QTY Starts: 15

MP #	Procedural Description	Work Step	Part # (BOM Qty)	Lot #	Qty. Rejected	Qty. Accepted	Initials (Each Operator)
	Advance Guidewire & Suture	5.1.20	Guidewire ~~Feeder~~ Advancer Ass'y DRW-~~0136~~ 0191 (1)	MJ 05APR2021	0	15	EV
	Verify needles are completely below surface after Plunger retraction	5.1.23	M-Close Handle Assembly DRW-0052 (1)		0	15	EV
	Remove Suture	5.1.25			0	15	EV
	Repeat step 5.1.19 – 5.1.25 on opposite port	5.1.26			0	15	EV
	Trocar test	5.1.28			0	15	EV
	Flip the Limit Lever up	5.1.29			0	15	EV

Work step tables shall be completed and initialed by operator performing procedure.

TOTAL Work Order (filled by production personnel)	Total Qty. Released	Date	Initial
	15	05 APR2021	AH

Production Traveler Review	Initials	Date
Production Supervisor (or Designee)		05 apr 2021
Quality Supervisor (or Designee)		05 APR 2021

Certificate of Processing

STERIS

Prepared for NEW WAVE ENDO

Radiation Request ID: 45389

P.O. #: 20511

Unit ID	Item Information	Quantity	UOM	Dose in Kilogray (in kGy) Specified Dose Min.	Specified Dose Max.	Delivered Dose Min.	Delivered Dose Max.	Exposure Time In Minutes
001	Product Code: See Customer Item ID Cust Item ID: 27-101 Lot Number: D0521 Description: M-Close Kit Comments: Product Meets Customer specifications; zero nonconformities occurred during this irradiated run	1	CS	10.20	12.40	10.29	10.65	73

Signature Manifest

Reviewed and E-Signed By

✓ ***Herolt, Daniel (QS & RC Technician I)***

Document Content Revision: 1

Signed On 4/16/2021 at 8:28 AM

UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
Radiation Technology Center
2500 Commerce Drive
Libertyville, IL 60048
Phone: 847-247-4782

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

STERIS

STERIS Dosimetry Record

Prepared for NEW WAVE ENDO

Radiation Request ID 45389

Date Prepared: 4/16/2021 8:26:45AM

Processing Location: **Radiation Technology Center**
Irradiator: **234, Nordion Cobalt-60 Irradiator #234**

Unit ID: 001

Coordinate	Barcode ID	Read By	Read Date	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
TC	0BX592073974	wwitcraf	04/15/2021 19:37:15	TH0075	0152	10.65	10.65
RBL	0BX592073980	wwitcraf	04/15/2021 19:34:40	TH0075	0152	10.33	10.33
EC	0BX592073985	wwitcraf	04/15/2021 19:38:38	TH0075	0152	10.29	10.29
FBR	0BX592001356	wwitcraf	04/15/2021 19:39:12	TH0075	0152	10.31	10.31
FTL	0BX592073975	wwitcraf	04/15/2021 19:37:53	TH0075	0152	10.55	10.55

Minimum Dose for Unit (kGy): 10.29

Maximum Dose for Unit (kGy): 10.65

Signature Manifest

Prepared By:
Walter Witcraft (Radiation Technician II)
Signed On 4/15/2021 at 2:39 PM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Herolt, Daniel (QS & RC Technician I)
Signed On 4/16/2021 at 8:26 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

STERIS

Applied Sterilization Technologies

05/04/2021
Document ID: 10338z

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

RADIATION REQUEST FORM

Radiation Center
Gamma – Americas (Libertyville, Illinois Radiation Technology Center)

STEP 1: Contact Details

PO #
20511

Email
martin.singer@newwaveendo.com

Additional Emails
martin.singer@newwaveendo.com

Product Received From (Originator):

Originator Company Name
New Wave Endo

Originator Address
6601 Lyons Road
Unit D8
Coconut Creek, Florida 33073
United States

Originator Contact Name
Martin Singer

Originator Email
martin.singer@newwaveendo.com

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

Originator Phone
9548060032

Product Belongs to (Customer):

Customer Contact Details
Same as Originator

Send Invoice to (Party to be billed):

Invoice Contact Details
Same as Originator

Ship Irradiated Product to:

Ship Irradiated Product to
None of the Above

Ship to Company Name
LGGS Florida

Shipping Address and Company Name
15370 CR 565A
Suite A
Groveland, FL 34736
United States

Shipping Contact Name
Ann Quiroz

Shipping Email
lggsflorida@yahoo.com

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

Shipping Phone
3522420057

STEP 2: Recipient of Transmittal Information

Original Certificate of Processing
Originator

Copy of Certificate of Processing
Originator

Dosimetry Record?
Yes

Radiation Request Form returned to
Originator

STEP 3: Shipping Information

Ship Via
Customer arranged courier

Select courier
UPS

UPS Shipping
2 Day Air

UPS Account #
59087E

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

STEP 4: Test Details

Type of Testing
Dose Verification (Dose Audit/Dose Establishment)

Protocol
No

Product Classification
Medical Device

Certification/License Requirements
- ISO11137

Hazardous Material?
No

STEP 5: Product Information

Internal Dosimeter
Some package configurations may require the placement of an internal dosimeter to monitor the minimum dose location. I hereby give approval to place internal dosimeters as needed. If product is packaged in a manner that will not allow the placement and retrieval (post-irradiation) of an internal dosimeter, I give approval to repackage the contents or open any secondary packaging to accommodate this placement as needed.

Product Information

# of Cartons	Dimensions (L x W x H)	Weight	Dose Range Min (kGy)	Dose Range Max (kGy)	Lot Number	Product Code	Description

STERIS
Applied Sterilization Technologies

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

05/04/2021
Document ID: 10338z

1	13 X 13 X 13	7	10.2	12.4	D0521	27-101	M-Close Kit

Special Instructions
Open shipper box and remove three 5-unit boxes for irradiation dosing. Following irradiation, replace back into shipper box and forward to LGGS Florida for sterility test.

Processing Information
- Routine Processing (4-7 business days) $1610.00

STERIS AST Quote Provided By: Josh Zerr

Date: 4/5/21

(Provided quote good for 30 days)

Customer Approval Signature: Martin Singer, Director of Quality

Date: 05 APR 2021

(Product cannot be processed without a signature)

Net Terms 30 days, unless otherwise contracted

Please sign AFTER STERIS AST has completed pricing information & has faxed to you for your approval... THANKS, STERIS AST liability under RRF limited to $500 unless otherwise specified in processing agreement. In no event shall STERIS AST be liable for any special, consequential, or exemplary damages.

STERIS AST Quality Assurance Reviewed By:

Date:

ATTACHMENT C

Bioburden Report

(4 pages)

LGGS Florida, Inc.
Bioburden Test Report

SPONSOR: New Wave Endo
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073
Attn: Martin Singer

Lab No.: F21-0580-00
P.O. No.: 20504
Lot No.: C1521-1
Date Received: 03-24-21

Test Article: M-Close Kit, REF 27-101

Condition of Test Article at Receipt: Good

Procedure: For complete details, see Bioburden Test Specification No. B-NWE-001-00

Results: Sample Number	Total Recoverable *Aerobic Bioburden* as CFU's per sample	Total Recoverable *Fungi Bioburden* as CFU's per sample
1	26	16
2	22	12
3	30	12
4	32	6
5	18	26
6	40	14
7	54	16
8	90	10
9	22	12
10	32	8
Number of Products Tested:	10	10
Ave. Colony Forming Units:	47.6	17.2
Standard Deviation:	21.4	5.5
PBW Negative Control:	Negative	Negative

Comments: A recovery factor of 1.3 was applied to the overall averages.

Deviations: None

Completed: 03-31-21 Tech: DJ/VS Approved by: _____
Technical Manager or Deputy

LGGS Florida, Inc.
Bioburden Test Report

SPONSOR: New Wave Endo
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073
Attn: Martin Singer

Lab No.: F21-0581-00
P.O. No.: 20504
Lot No.: C1521-2
Date Received: 03-24-21

Test Article: M-Close Kit, REF 27-101

Condition of Test Article at Receipt: Good

Procedure: For complete details, see Bioburden Test Specification No. B-NWE-001-00

Results: Sample Number	Total Recoverable *Aerobic Bioburden* as CFU's per sample	Total Recoverable *Fungi Bioburden* as CFU's per sample
1	60	6
2	28	12
3	14	6
4	26	14
5	38	12
6	32	22
7	22	18
8	46	24
9	26	24
10	32	4
Number of Products Tested:	10	10
Ave. Colony Forming Units:	42.1	18.5
Standard Deviation:	13.0	7.6
PBW Negative Control:	Negative	Negative

Comments: A recovery factor of 1.3 was applied to the overall averages.

Deviations: None

Completed: 03-31-21 Tech: DJ/VS Approved by: _____
Technical Manager or Deputy

LGGS Florida, Inc.
Bioburden Test Report

SPONSOR: New Wave Endo
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073
Attn: Martin Singer

Lab No.: F21-0582-00
P.O. No.: 20504
Lot No.: C1521-3
Date Received: 03-24-21

Test Article: M-Close Kit, REF 27-101

Condition of Test Article at Receipt: Good

Procedure: For complete details, see Bioburden Test Specification No. B-NWE-001-00

Results: Sample Number	Total Recoverable *Aerobic Bioburden* as CFU's per sample	Total Recoverable *Fungi Bioburden* as CFU's per sample
1	30	68
2	34	16
3	278	84
4	302	44
5	28	24
6	180	30
7	56	44
8	34	40
9	36	20
10	54	24
Number of Products Tested:	10	10
Ave. Colony Forming Units:	134.2	51.2
Standard Deviation:	108.4	22.0
PBW Negative Control:	Negative	Negative

Comments: A recovery factor of 1.3 was applied to the overall averages.

Deviations: None

Completed: 03-31-21 Tech: DJ/VS Approved by: _____
Technical Manager or Deputy

FORM O-0055-1
Revision 005

TEST REQUEST FORM

☐ 3335 E. Miraloma Ave.
140
Anaheim, CA 92806
Phone: (714) 223-0800
Fax: (714) 223-0801
Email: cs@lggsinc.com

☑ 15370 CR 565A
Suite A
Groveland, FL 34736
Phone: (352) 242-0057
Fax: (352) 242-4741
Email: lggsflorida@gmail.com

PLEASE FILL IN PERTINENT INFORMATION LEGIBLY. SUBMIT ONE COMPLETED FORM WITH EACH SAMPLE TO BE TESTED. PURCHASE ORDER NO. AND SIGNED TEST REQUEST FORM ARE BOTH REQUIRED FOR TESTS TO BE SCHEDULED. SEND SAMPLES AND COMPLETED FORM TO PROPER ADDRESS FOR TESTING (LISTED ABOVE).

(Lab Use Only)

Lab Number: _____

Date: _____ Received in Good Condition ☐ YES ☐ NO

Logged in by: _____ Number of samples received: _____

Notes: _____

CUSTOMER CONTACT INFORMATION **Purchase Order** _____

Company Name	New Wave Endo	Contact Person	Martin Singer
Street Address	6601 Lyons Road, Unit D8	Phone/Ext	954 806 0032
City, State, Zip code	Coconut Creek, FL 33073	Email	martin.singer@newwaveendo.com

CUSTOMER BILLING INFORMATION ☑ same as customer contact information

Company Name		Contact Person	
Street Address		Phone/Ext	
City, State, Zip code		Email	

TEST ARTICLE DESCRIPTION (use EXACT wording desired on Technical Report)

M-Close Kit, REF 27-101 corrected typo MJ. 01APR2021

Sample ID/Batch/Lot number: C1521-1, C1521-2, ~~C15221-3~~ C1521-3 ☐ N/A

- ☑ New product test submission
- ☐ New product to existing, reference specification: _____
- ☐ Existing product, reference specification: _____

Sample Storage Condition
- ☑ Room Temperature
- ☐ Refrigerated
- ☐ Freezer
- ☐ Other

Sample Disposition (default is discard)
- ☑ Discard Samples
- ☐ Return Samples
- ☐ Return Shipping Container
- ☐ Pick up

Tests Requested:

Test Code: MB-005 Test description: Total Aerobic and Total Fungi - 3 lots 10 samples ea.

Special Instructions: Open sterile pouch and test all contents

Customer Signature: Martin Singer Digitally signed by Martin Singer Date: 2021.03.17 10:07:57 -04'00' Date: 17MAR2021

ATTACHMENT D

B/F Irradiation Record
(3 units of Lot C1521-4 irradiated inside 1 of 7 cartons of Lot C2321)

(3 pages)

See also page 2 of 5 for DHR C1521-4 in Attachment B

STERIS: Gamma Certificate Of Processing

Prepared for: NEW WAVE ENDO (8908)

Gamma Process Run ID: 1063-2754A

Product Code	Lot Number	Quantity	UOM
M-Close 27-101	C2321	7	Case

Processing Run Start Date: 30-Mar-21 02:21 AM

Approx. Downtime (hours): 0.10

Processing Run End Date: 30-Mar-21 05:25 AM

Minimum Specified Dose (kGy):	**30.0**	**Minimum Delivered Dose (kGy):**	**39.3**
Maximum Specified Dose (kGy):	**50.0**	**Maximum Delivered Dose (kGy):**	**46.5**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By: **Jasmin Cuevas (QS & RC Technician I)**

Date/Time E-Signed: 2021-03-30 10:49 AM

Document Content Revision: 1

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

1880 Industrial Dr
Libertyville IL 60048
Phone: 847-367-1911

STERIS: Gamma Dosimetry Record
NEW WAVE ENDO (8908)

Irradiator / Method: IR-139 - ON-STD

Run ID
1063-2754A

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)	Comment
1	1	1C1	0BZ608022366	TH0077	0391	39.7	39.7	
1	2	1C3	0BZ608022249	TH0077	0391	39.6	39.6	
1	3	1C5	0BZ608022273	TH0077	0391	40.0	40.0	
1	4	1CEOB	0BZ608022328	TH0077	0391	40.8	40.8	
1	5	1 E5	0BZ608022012	TH0077	0391	43.3	43.3	
1	6	2A5	0BZ608022350	TH0077	0391	45.4	45.4	
1	7	2 E5	0BZ608022024	TH0077	0391	45.2	45.2	
1	8	3A5	0BZ608022127	TH0077	0391	45.7	45.7	
1	9	3 E5	0BZ608022036	TH0077	0391	46.5	46.5	
1	10	4 E5	0BZ608022040	TH0077	0391	46.0	46.0	
1	11	9.8C5	0BZ608022339	TH0077	0391	40.1	40.1	
1	12	12.8C3	0BZ608022107	TH0077	0391	39.3	39.3	
1	13	12.8C5	0BZ608022037	TH0077	0391	39.8	39.8	
1	14	13CEOB	0BZ608022023	TH0077	0391	40.2	40.2	
1	15	15.7C3	0BZ608022050	TH0077	0391	40.4	40.4	
1	16	15.7C5	0BZ608022375	TH0077	0391	39.4	39.4	
1	17	17CEOB	0BZ608022347	TH0077	0391	40.3	40.3	
1	18	19C1	0BZ608022343	TH0077	0391	40.9	40.9	
1	19	21CEOB	0BZ608022352	TH0077	0391	41.0	41.0	
1	20	TBA5	0BZ608022390	TH0077	0391	42.2	42.2	
1	21	TBE5	0BZ608022359	TH0077	0391	41.8	41.8	

Minimum Dose for Record (kGy): 39.3

Maximum Dose for Record (kGy): 46.5

STERIS: Gamma Dosimetry Record
NEW WAVE ENDO (8908)

Irradiator / Method: IR-139 - ON-STD

Run ID
1063-2754A

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)	Comment

Signature Manifest

Prepared By: **Matthew Thornton (Operator I)**

Date/Time E-Signed: 2021-03-30 09:16 AM

Document Content Revision: 1

Processing Location

1880 Industrial Dr
Libertyville IL 60048
Phone: 847-367-1911

ATTACHMENT E

B/F Report for Lot C1521-4

(1 page)

LGGS Florida Technical Report
Method Suitability Test – 3 Organisms

SPONSOR: New Wave Endo
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073
Attn: Martin Singer

Lab No.: F21-0625-00
P.O. No.: 20513
Lot No.: C1521-4
Date Received: 04-01-21

Test Article: M-Close Kit, REF 27-101 Sterilized

Condition of Test Article: Good

Procedure: Sterile samples were selected for Method Suitability Test testing (following successful completion of sterility testing). Three (3) 400mL SCDB cultures from each product type and three (3) 400mL THIO cultures from each product type were inoculated with appropriate test organism.

Positive controls were set up simultaneously with each organism seeded into the culture medium. All SCDB cultures were incubated at 22.5 ± 2.5°C and all THIO cultures were incubated at 32.5 ± 2.5°C until positive for microbial growth or for a maximum of five (5) days. The standard plate count method was used to determine the microbial count (CFU's) challenging each test or control system.

Organisms:	ATCC	Population:	SCD Sample:	SCD Control:
Bacillus spizizenii *Bs 4861094*	6633	33	1+ / 04-05-21	1+ / 04-05-21
Candida albicans *Ca 44311032*	10231	24	1+ / 04-05-21	1+ / 04-05-21
Aspergillus brasiliensis *Ab 3929771*	16404	21	1+ / 04-05-21	1+ / 04-05-21

Conclusion: Under the conditions of this USP test, bacteriostatic/fungistatic characteristics were not shown to be associated with the test article.

Comments: None

Deviations: None

Date: 04-05-21 Tech: LY/VS Approved by: _____
Technical Manager (or deputy)

ATTACHMENT F

Bioburden Recovery Validation Final Report

(6 pages)

Lab No. F21-0583-01

FINAL REPORT
Bioburden Recovery Validation of
New Wave Endo Surgery's
M-Close Kit, REF 27-101

SPONSOR:

New Wave Endo Surgery
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073

PREPARED BY:

LGGS Florida, Inc.
15370 County Road 565A, Suite A
Groveland, FL 34736

FINAL REPORT
Bioburden Recovery Validation of
New Wave Endo Surgery's
M-Close Kit, REF 27-101

SPONSOR:

New Wave Endo Surgery
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073

I. **Purpose:**

The purpose of this study was to establish exhaustive bioburden recovery efficiency percentages and document estimated recovery efficiencies for New Wave Endo Surgery's M-Close Kit, REF 27-101

II. **Materials:**

A. Device(s) intended for testing
B. Other materials as specified in the bioburden test specification

III. **Background:**

Bioburden is defined as the population of viable microorganisms present in or on a finished product just prior to sterilization.

Recovery of microorganisms from product during bioburden test procedures may be accomplished utilizing several methodologies. The choice of an appropriate procedure and recovery fluid depends upon product design and composition. The chosen recovery method must be validated to determine efficacy and reproducibility for each product or family of products. During the validation procedure, a recovery factor must be determined, however, it may not be necessary to apply the recovery factor for routine use in some situations.

For the purpose of enumerating bioburden levels associated with the for New Wave Endo Surgery's M-Close Kit, REF 27-101, a combined extraction procedure incorporating 10 minutes of sonication at a nominal frequency of 24 KHz followed by 30 minutes of shaking on a mechanical shaker, yielding 170-240 oscillations per minute, was selected. This procedure (sonication/shaking) has historically resulted in maximum recovery using diverse product materials and configurations and was selected for use with the New Wave Endo Surgery's M-Close Kit, REF 27-101, due to the thickness of product which prevents blending and the absence of attributes which would be expected to interfere with the effectiveness of standard industrial immersion/shake recovery techniques.

Products were processed using the largest possible SIP of 1.0 (entire device).

The extraction fluid chosen for these tests was Phosphate Buffered Water (PBW) which was employed due to its neutral pH, osmolarity and buffering capacity. Additionally, PBW has been demonstrated to neither promote nor inhibit growth of microorganisms.

Total aerobic bioburden was enumerated utilizing Tryptic Soy Agar (TSA) and incubation periods of 72 hours. Total Fungi was enumerated using Saboraud Dextrose Agar (SDA) and incubated at 20-25°C for 120 hours. The membrane filtration technique was employed.

Products represented in routine bioburden auditing were reviewed in this study. Changes in procedures or product will be evaluated for impact on recovery efficacy and will be revalidated if necessary.

The method chosen to review bioburden recovery efficacy during this study was the exhaustive recovery method. Although the spore inoculation method is a widely used validation method, severe limitations such as encrustation, adhesion of the suspension, spore clumping (especially with silicone surfaces), standard deviation of the inoculum and lack of information comparing spore inoculation to natural bioburden attachment, make it undesirable for this evaluation.

Exhaustive recovery required performing the entire extraction procedure on each device two (2) additional times following its original extraction. Each time, the extraction fluid was totally removed from the device and enumerated. The results accumulated from the consecutive recoveries were then analyzed. The efficacy was then estimated based upon the initial device counts and the estimated final device counts.

IV. Results:

A. Total Aerobic Bioburden

Treatment	1	2	3	4	5	Mean Colony Average
1	26	22	30	32	18	25.6
2	6	8	8	6	12	8.0
3	0	0	0	0	0	0.0
Total Colony Count	32	30	38	38	30	

	1	2	3	4	5
First Treatment	26	22	30	32	18
Total	32	30	38	38	30
% Removal	81.3	73.3	78.9	84.2	60.0

Average Recovery: 75.5 (5 samples) Correction Factor: 100/77.5 = 1.3

B. Total Recoverable Fungi

Treatment	1	2	3	4	5	Mean Colony Average
1	16	12	12	6	26	14.4
2	6	4	2	2	6	4.0
3	0	0	0	0	0	0.0
Total Colony Count	22	16	14	8	32	

	1	2	3	4	5
First Treatment	16	12	12	6	26
Total	22	16	14	8	32
% Removal	72,7	75.0	85.7	75.0	81.2

Average Recovery:	81.2	(5 samples)	Correction Factor: 100/81.2 =	1.2

V. References:

A. LGGS Inc. Bioburden Specification.
B. ANSI/AAMI/ISO 11737-1, Sterilization of Healthcare Products-Microbiological Methods-Part 1: Determination of the Population of Microorganisms on Product, Association for the Advancement of Medical Instrumentation, 2018.

VI. Approvals:

Prepared by: Valerie Salvati Date: 3-31-21

Approved by: Date: 3.31.21

Approved by: Date: 01 APR 2021
New Wave Endo Surgical

LGGS Florida, Inc.
Bioburden Test Report

SPONSOR: New Wave Endo
6601 Lyons Road, Unit D8
Coconut Creek, FL 33073
Attn: Martin Singer

Lab No.: F21-0583-00
P.O. No.: 20504
Lot No.: C1521-1
Date Received: 03-24-21

Test Article: M-Close Kit, REF 27-101

Condition of Test Article at Receipt: Good

Procedure: For complete details, see Bioburden Test Specification No. B-NWE-001-00

Wash 1:

Results: Sample Number	Total Recoverable Aerobic Bioburden as CFU's per sample	Total Recoverable Fungi Bioburden as CFU's per sample
1	26	16
2	22	12
3	30	12
4	32	6
5	18	26
Number of Products Tested:	5	5
Ave. Colony Forming Units:	25.6	14.4
Standard Deviation:	5.7	7.4
PBW Negative Control:	Negative	Negative

Wash 2:

Results: Sample Number	Total Recoverable Aerobic Bioburden as CFU's per sample	Total Recoverable Fungi Bioburden as CFU's per sample
1	6	6
2	8	4
3	8	2
4	6	2
5	12	6
Number of Products Tested:	5	5
Ave. Colony Forming Units:	8.0	4.0
Standard Deviation:	2.4	2.0
PBW Negative Control:	Negative	Negative

Wash 3:

Results: Sample Number	Total Recoverable Aerobic Bioburden as CFU's per sample	Total Recoverable Fungi Bioburden as CFU's per sample
1	<2	<2
2	<2	<2
3	<2	<2
4	<2	<2
5	<2	<2
Number of Products Tested:	5	5
Ave. Colony Forming Units:	0.0	0.0
Standard Deviation:	0.0	0.0
PBW Negative Control:	Negative	Negative

Comments: None

Deviations: None

Completed: 03-31-21 Tech: DJ/VS Approved by: _____
Technical Manager or Deputy

ATTACHMENT G

Verification Dose Applied

(7 pages)

Certificate of Processing

STERIS

Prepared for **NEW WAVE ENDO**

Radiation Request ID: **45389**

P.O. #: **20511**

Unit ID	Item Information	Quantity	UOM	Dose in Kilogray (in kGy) Specified Dose Min.	Specified Dose Max.	Delivered Dose Min.	Delivered Dose Max.	Exposure Time In Minutes
001	Product Code: See Customer Item ID Cust Item ID: 27-101 Lot Number: D0521 Description: M-Close Kit Comments: Product Meets Customer specifications; zero nonconformities occurred during this irradiated run	1	CS	10.20	12.40	10.29	10.65	73

Signature Manifest

Reviewed and E-Signed By

✓ ***Herolt, Daniel (QS & RC Technician I)***

Document Content Revision: 1

Signed On 4/16/2021 at 8:28 AM

UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
Radiation Technology Center
2500 Commerce Drive
Libertyville, IL 60048
Phone: 847-247-4782

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

STERIS

STERIS Dosimetry Record

Prepared for NEW WAVE ENDO

Radiation Request ID 45389

Date Prepared: 4/16/2021 8:26:45AM

Processing Location: **Radiation Technology Center**
Irradiator: **234, Nordion Cobalt-60 Irradiator #234**

Unit ID: 001

Coordinate	Barcode ID	Read By	Read Date	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
TC	0BX592073974	wwitcraf	04/15/2021 19:37:15	TH0075	0152	10.65	10.65
RBL	0BX592073980	wwitcraf	04/15/2021 19:34:40	TH0075	0152	10.33	10.33
EC	0BX592073985	wwitcraf	04/15/2021 19:38:38	TH0075	0152	10.29	10.29
FBR	0BX592001356	wwitcraf	04/15/2021 19:39:12	TH0075	0152	10.31	10.31
FTL	0BX592073975	wwitcraf	04/15/2021 19:37:53	TH0075	0152	10.55	10.55

Minimum Dose for Unit (kGy): 10.29

Maximum Dose for Unit (kGy): 10.65

Signature Manifest

Prepared By:
Walter Witcraft (Radiation Technician II)
Signed On 4/15/2021 at 2:39 PM
UTC / GMT Offset (hh:mm). -5:00

Approved By:
Herolt, Daniel (QS & RC Technician I)
Signed On 4/16/2021 at 8:26 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

STERIS

Applied Sterilization Technologies

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

45389

05/04/2021
Document ID: 10338z

RADIATION REQUEST FORM

Radiation Center
Gamma – Americas (Libertyville, Illinois Radiation Technology Center)

STEP 1: Contact Details

PO #
20511

Email
martin.singer@newwaveendo.com

Additional Emails
martin.singer@newwaveendo.com

Product Received From (Originator):

Originator Company Name
New Wave Endo

Originator Address
6601 Lyons Road
Unit D8
Coconut Creek, Florida 33073
United States

Originator Contact Name
Martin Singer

Originator Email
martin.singer@newwaveendo.com

RECEIVED APR 07 2021

45389

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

05/04/2021
Document ID: 10338z

Originator Phone
9548060032

Product Belongs to (Customer):

Customer Contact Details
Same as Originator

Send Invoice to (Party to be billed):

Invoice Contact Details
Same as Originator

Ship Irradiated Product to:

Ship Irradiated Product to
None of the Above

Ship to Company Name
LGGS Florida

Shipping Address and Company Name
15370 CR 565A
Suite A
Groveland, FL 34736
United States

Shipping Contact Name
Ann Quiroz

Shipping Email
lggsflorida@yahoo.com

45389

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

05/04/2021
Document ID: 10338z

Shipping Phone
3522420057

STEP 2: Recipient of Transmittal Information

Original Certificate of Processing
Originator

Copy of Certificate of Processing
Originator

Dosimetry Record?
Yes

Radiation Request Form returned to
Originator

STEP 3: Shipping Information

Ship Via
Customer arranged courier

Select courier
UPS

UPS Shipping
2 Day Air

UPS Account #
59087E

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

45389

STEP 4: Test Details

Type of Testing
Dose Verification (Dose Audit/Dose Establishment)

Protocol
No

Product Classification
Medical Device

Certification/License Requirements
- ISO11137

Hazardous Material?
No

STEP 5: Product Information

Internal Dosimeter
Some package configurations may require the placement of an internal dosimeter to monitor the minimum dose location. I hereby give approval to place internal dosimeters as needed. If product is packaged in a manner that will not allow the placement and retrieval (post-irradiation) of an internal dosimeter, I give approval to repackage the contents or open any secondary packaging to accommodate this placement as needed.

Product Information

# of Cartons	Dimensions (L x W x H)	Weight	Dose Range Min (kGy)	Dose Range Max (kGy)	Lot Number	Product Code	Description

STERIS

Applied Sterilization Technologies

STERIS AST Radiation Technology Center
Phone: (847) 247-4782
Email: RadiationTechTeam@steris.com

45389

05/04/2021
Document ID: 10338z

1	13 X 13 X 13	7	10.2	12.4	D0521	27-101	M-Close Kit

Special Instructions

Open shipper box and remove three 5-unit boxes for irradiation dosing. Following irradiation, replace back into shipper box and forward to LGGS Florida for sterility test.

Processing Information

- Routine Processing (4-7 business days) $1610.00

STERIS AST Quote Provided By: Josh Zerr

Date: 4/5/21

(Provided quote good for 30 days)

Customer Approval Signature: Martin Singer, Director of Quality

Date: 05 APR 2021

(Product cannot be processed without a signature)

Net Terms 30 days, unless otherwise contracted

Please sign AFTER STERIS AST has completed pricing information & has faxed to you for your approval... THANKS, STERIS AST liability under RRF limited to $500 unless otherwise specified in processing agreement. In no event shall STERIS AST be liable for any special, consequential, or exemplary damages.

STERIS AST Quality Assurance Reviewed By:

Date: 4.8.21

ATTACHMENT H

Sterility Test Result for Lot D0521

(2 pages)

LGGS Florida, Inc. Technical Report

SPONSOR:	New Wave Endo	Lab No.:	F21-0723-00
	6601 Lyons Road, Unit D8	P.O. No.:	20512
	Coconut Creek, FL 33073	Lot No.:	D0521
	Attn: Martin Singer	Date Received:	04-20-21

Sterility Test

Testing Follows USP Method When Applicable

Test Article: M-Close Kit, REF 27-101

Condition of Test Article at Receipt: Good

Test Article Submitted:

No. of Products:	No. Spore Strips:	No. Inoculated Product:
10	N/A	N/A

Test Start Date:	Test Termination Date:	Proc./Test Method Used:
04-21-21	05-05-21	NWE-001-00

Sterility Test Results

Note: Test Article Identity Maintained as Submitted by Sponsor

No. Positive:	No. Articles Submitted:	Articles Tested:	(ml) SCDB:	(ml) FT
0	10	WP	400	N/A

Test Article as submitted found to be: Sterile

Media Lot: C3032321

NS=Not Supplied SCDB=Soybean Casein Digest Broth FT=Fluid Thioglycollate

Comments: None

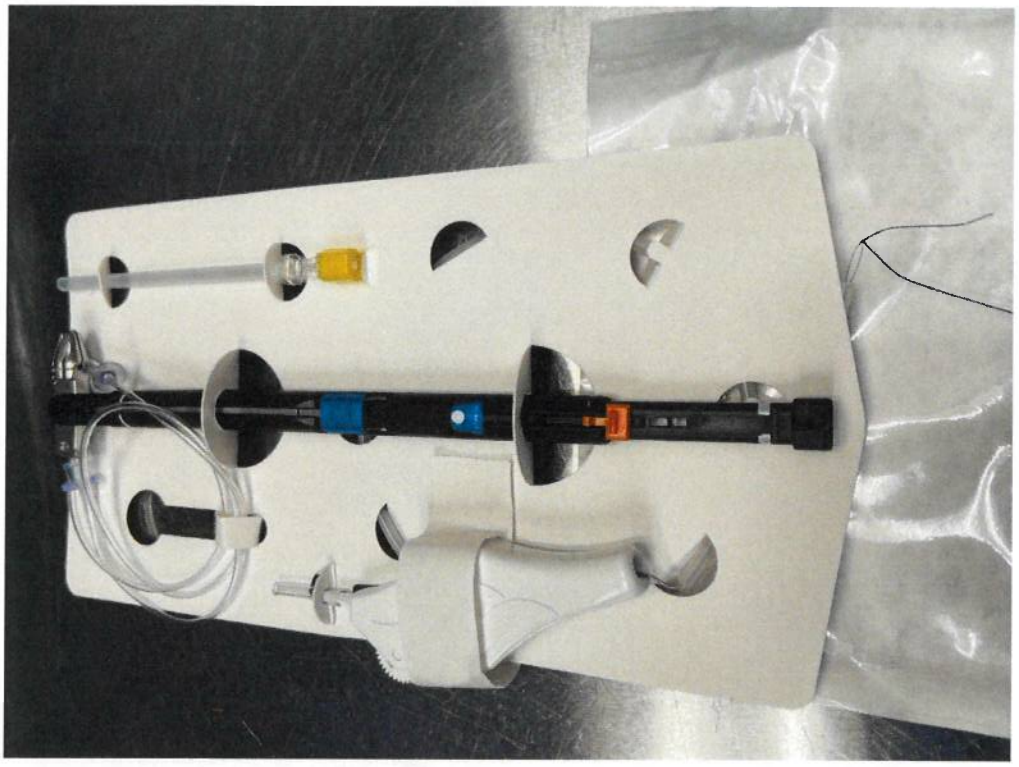
Deviations: None

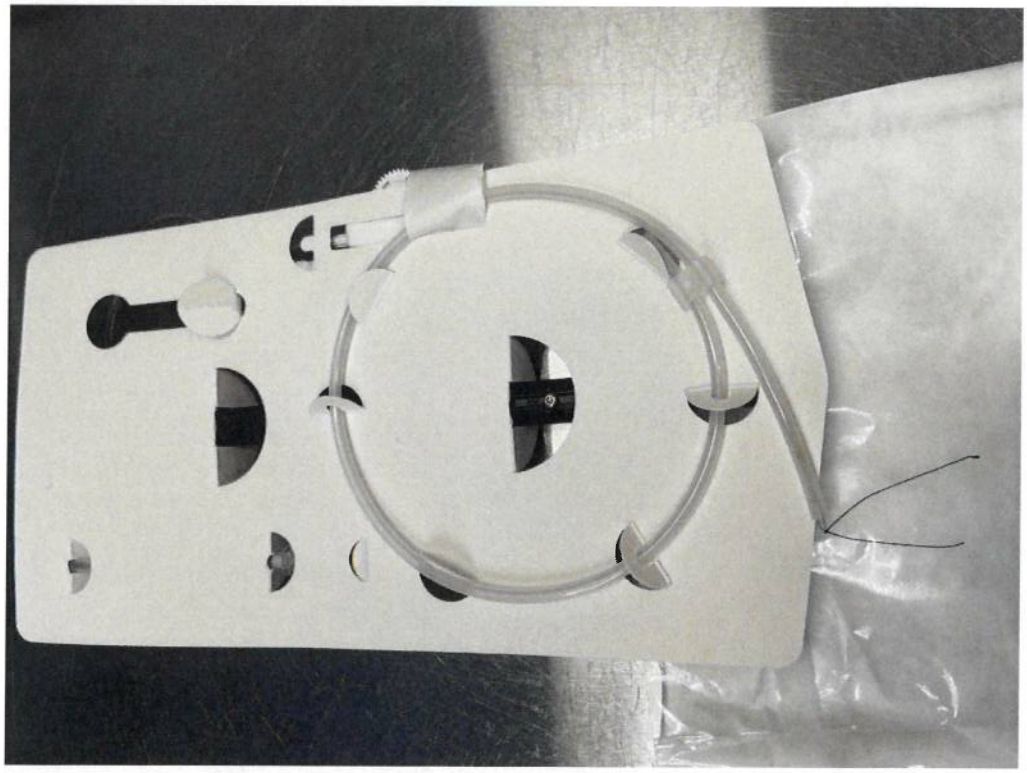
Completed: 05-05-21 Tech: LY/VS Approved by: _____

Technical Manager (or deputy)

LOT D0521

TOP SIDE CARD MOUNTING





REVERSE SIDE CARD MOUNTING